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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,191	03/03/2004	Chun-Ying Huang	624-040488	4926
<div>7590 04/30/2007 WEBB ZIESENHEIM LOGSDON ORKIN & HANSON, P.C. 700 Koppers Building 436 Seventh Avenue Pittsburgh, PA 15219-1818</div>			<div>EXAMINER JONES, DAMERON LEVEST</div> <div>ART UNIT 1618</div> <div>PAPER NUMBER</div>	
			<div>MAIL DATE 04/30/2007</div> <div>DELIVERY MODE PAPER</div>	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/792,191	Applicant(s) HUANG ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/16/07; 1/6/06; & 8/25/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/16/07; 1/6/06; & 8/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

APPLICANT'S INVENTION

1. Applicant's invention is directed pharmaceutical compositions and methods of making those compositions.

Note: Claims 1-17 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group I filed 2/14/07 is acknowledged. The traversal is on the ground(s) that searching the full scope of the claims would not create an undue burden on the Examiner. In addition, Applicant asserts that the species, As₂O₃, As₂S₃, and As₂S₂ are not patentable distinct because they all are effective in the treatment of leukemia. Also, Applicant summarizes various prior art documents as they relate to the instant invention. This is found non-persuasive because as stated in the restriction requirement mailed 1/11/07, the compounds may be made by materially different process. For example, the compounds of the instant invention may be made by the processes of claims 1 or 6, or by one of the processes disclosed in the prior art cited below. Furthermore, the claims are product-by-process claims. As a result, patentability of the claims are not limited to the manipulations of the recited steps when the prior art discloses the same product as that being claimed by Applicant. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the species As₂O₃ and liver tumors is acknowledged in the response filed 2/14/07.

WITHDRAWN CLAIMS

3. Claims 6-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

102 REJECTIONS

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Born et al (Naturwissenschaften, 1941, Vol. 29, pages 182-183).

Born et al disclose mouse experiments wherein radioactive arsenic is utilized. Sodium cacodylate was irradiated with slow neutrons and the radioactive arsenic was separated. The radioactive arsenic was in the form of an aqueous solution of As₂O₃. The radioactive As₂O₃ was administered to mice in food or by subcutaneous injection (see entire document, especially, abstract). Therefore both Born et al and Applicant disclose a radiolabeled arsenic-containing compound, As₂O₃, in combination with a pharmaceutically acceptable carrier. It should be noted that it would be inherent to a skilled practitioner in the art that the radioactive arsenic compound would emit gamma and beta particles because that is one of the properties of radioactive complexes (see Hawley's Condensed Chemical Dictionary, 12th edition by Richard Lewis, Sr., page 991

which defines the term 'radioisotope'. A copy of the dictionary entry is being mailed with this office action).

Note: Hawley's Condensed Chemical Dictionary, 12th edition by Richard Lewis, Sr., page 991 defines the term 'radioisotope' as an isotopic form of an element (either natural or artificial) that exhibits radioactivity. Radioisotopes are used as diagnostic and therapeutic agents in medicine, biological tracer studies, and for many industrial purposes. Artificial radioisotopes are made by neutron bombardment of stable isotopes in a nuclear reactor.

6. Claims 1- 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison et al (Can. J. Research, 1949, Vol. 27D, pages 265-269).

Morrison et al disclose the distribution of radioactive arsenic in the organs of insect larvae. Radioactive arsenic trioxide (As_2O_3) containing As^{76} was injected into larvae. The arsenic solution was prepared by combining active arsenic trioxide with other components including distilled water (see entire document, especially, abstract; page 265, 'Materials and Procedure'; page 266, 'Experimental Procedure', section 2).

Thus, both Applicant and Morrison et al disclose an injectable pharmaceutical composition comprising As_2O_3 where the ^{76}As isotope is utilized

COMMENTS/NOTES

7. The restriction mailed 1/11/07 was modified. Specifically, Group I should contain only claims 1-5 and Group II should contain claims 6-17. The reason for the change is

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because claims 10-17 depend upon claim 6. Therefore, they should properly be placed in Group II.

8. Applicant is respectfully requested to review MPEP 2113, which is directed to product-by-process claims. In particular, Applicant is reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious form a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In other words, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'D. L. Jones', is positioned above the printed name.

D. L. Jones
Primary Examiner
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April 23, 2007